

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AR BUTUS BIOPHARMA CORPORATION	:	
and GENEVANT SCIENCES GMBH,	:	
	:	
Plaintiffs,	:	CIVIL ACTION
	:	
v.	:	
	:	
MODERNA, INC. and MODERNATX, INC.,	:	NO. 22-252
	:	
Defendants.	:	

ORDER

AND NOW, this 20th day of June, 2024, upon consideration of the parties' discovery dispute letters (D.I. 285, 287, 294, 302, 331, 341, 345, 348), and following a discovery hearing held on June 13, 2024, I find the following:

Factual Background

1. During the course of the COVID-19 pandemic, Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Defendant" or "Moderna") brought to market an mRNA-based vaccine in an effort to combat the effect of the COVID-19 virus. Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") (collectively "Plaintiffs") claim that, in order for the vaccine to succeed, Moderna used a revolutionary lipid nanoparticle ("LNP") delivery platform—created and patented by Plaintiffs—without paying for it or requesting a license.
2. On February 28, 2022, Plaintiffs filed suit seeking compensation for the use of the patented technology they claim to have developed, alleging direct and indirect infringement on six different patents. Defendant counterclaims seeking declaratory judgments of noninfringement and invalidity.

3. With fact discovery having closed, the parties have raised multiple discovery disputes. On June 13, 2024, I held a hearing on those disputes.

Plaintiffs' Motion to Compel a Search of Stephane Bancel's Documents

4. The first discovery dispute concerns documents in the possession of Stephane Bancel, Defendant's Chief Executive Officer (D.I. 285). Plaintiffs previously sought discovery from Mr. Bancel, claiming that he possessed relevant, non-duplicative documents. Defendant objected, asserting that Plaintiffs failed to meet their burden of articulating particularized information that demonstrates the need for an expanded search beyond the ten custodians permitted under the Delaware Default Standard.
5. After a previous discovery hearing held in October 2023, wherein Mr. Bancel's documents were raised, I denied Plaintiffs' request without prejudice to their right to re-raise the issue at a later date following Plaintiffs' review of discovery received.
6. Plaintiffs have now renewed their motion for a targeted search of Mr. Bancel's documents, asserting that he is a key source of significant relevant information. Defendant disagrees and contends that any information in Mr. Bancel's possession is redundant of what Plaintiffs have received from other custodians.
7. I recognize that many of Mr. Bancel's relevant documents may indeed overlap with discovery already produced through other custodians. Thus, the costly burden of a broad search of Mr. Bancel's documents is not justified, and Plaintiffs' Motion to Compel a Search of Stephane Bancel's documents will be denied without prejudice.
8. However, at the most recent discovery hearing Defendant could not confirm that Bancel had *no* non-duplicative information in his possession regarding the topics identified by Plaintiffs. To ensure that Plaintiffs' have access to the unique information within Mr. Bancel's knowledge, on or before July 17, 2024, Defendant shall make Mr. Bancel available for a deposition, which shall exceed no more than four (4) hours, and which shall be limited to the following topics:

- Mr. Bancel's communications with the Government that bear on Defendant's assertion of a defense pursuant to 28 U.S.C. § 1498, and about which Mr. Bancel is the only Moderna employee who would have knowledge of those communications;
 - Mr. Bancel's communications with Plaintiffs' predecessors regarding licensing Plaintiffs' technology where Mr. Bancel is the only Moderna employee who would have knowledge of those communications;
 - Mr. Bancel's communications with counter-parties to its executive licensing agreements where Mr. Bancel is the only Moderna employee who would have knowledge of those communications.
9. If, following the deposition, Plaintiffs can specifically identify documents in Mr. Bancel's possession that are relevant to these topics, which have not previously been produced by Defendant, Plaintiffs may—after meeting and conferring with Defendant—renew their request for such documents.

Plaintiffs' Motion Regarding Rule 30(b)(6) Disputes

10. The parties' second dispute concerns Plaintiffs' request for Rule 30(b)(6) depositions and the scope of the appropriate topics. Plaintiffs have filed a letter motion seeking to resolve this dispute (D.I. 287).
11. The first topic concerns Plaintiffs' request for testimony as to “[t]he experiments, methods, and results used, referenced, and/or reported in” seven publications authored by Defendant's scientists.
12. At the June 13, 2024 discovery hearing, Plaintiffs agreed to withdraw this request but asked that I issue an order precluding Defendant from offering testimony or evidence on the content of these publications. As such a ruling is more appropriately made in the context of either summary judgment briefing or trial, I decline to issue the requested order at this time. Defendant, however, is advised that if it raises testimony or evidence regarding any publications not disclosed to Plaintiffs in the course of discovery, I will strongly consider Plaintiffs' objections on the basis of unfair surprise. I will otherwise deny Plaintiffs' request to compel Rule 30(b)(6) deposition testimony on this topic as moot.

13. The second Rule 30(b)(6) topic at issue concerns discovery regarding Defendant's communications with any person or entity affiliated with the United States Government involving 28 U.S.C. § 1498, the decision to include the Federal Acquisition Regulation clause in the contract, the Government's decision to file a Statement of Interest in the case, and any relationship of that decision to Defendant's commitment to provide the Accused Product free to uninsured people.
14. By way of brief background, Defendant originally moved to dismiss the Complaint under § 1498, contending that Plaintiffs' sole and exclusive remedy for its patent infringement allegations was against the United States Government. Section 1498 "provides a cause of action against the United States (waiving sovereign immunity) for a patent owner to recover damages for the unauthorized use or manufacture of a patented invention '*by or for* the United States.'" Astornet Techs. Inc. v. BAE Sys., Inc., 802 F.3d 1271, 1277 (Fed. Cir. 2015) (internal quotations omitted) (emphasis in original). For claims that fall within the statute's ambit, the remedy against the United States is exclusive. Id. I denied that Motion on the ground that application of this defense required resolution of multiple factual disputes. Arbutus Biopharma Corp. v. Moderna, Inc., 638 F. Supp. 3d 397 (D. Del. 2022).
15. Defendant continues to press its affirmative defense under § 1498. At the June 13, 2024 hearing, Defendant confirmed that, to prove this defense, it intends to rely on both the C-100 contract with the Government, which includes the Federal Acquisition Regulation ("FAR"), and the Government's Statement of Interest provided to the Court in February 2023.
16. To that end, Plaintiffs are entitled to explore the basis for the inclusion of the FAR, and the impetus for the Government's decision to provide the Statement of Interest after the initiation of this litigation and my ruling on the motion to dismiss. Plaintiffs have represented that they attempted to obtain this information from the Government but were advised that they would have to seek it from Defendant directly. I find that the burden on Defendant to provide a witness

who can testify on the information is minimal at best. Accordingly, I will grant Plaintiff's request to compel Rule 30(b)(6) testimony on 28 U.S.C. § 1498, the decision to include the FAR clause in the contract, the Government's decision to file a Statement of Interest in the case, and any relationship of that decision to Defendant's commitment to provide the Accused Product free to uninsured people.

Plaintiffs' Motion Regarding U.S. Based Sales of the Accused Product

17. Plaintiffs' third letter motion (D.I. 331) seeks discovery regarding sales of the Accused Product that Defendant characterized as "foreign sales" because the product was manufactured and delivered abroad.
18. I previously addressed this dispute and directed Plaintiffs to propound specific interrogatories about such sales that are narrowly tailored to the factors described in Halo Electronics, Inc. v. Pulse Electronics, Inc., 831 F.3d 1369 (Fed. Cir. 2016). I noted that if, after review of Defendant's responses, Plaintiffs could demonstrate that a specific sale could be deemed a "U.S. sale," they could renew their request for documents as to that sale.
19. Plaintiffs have now returned, noting that under Federal Circuit precedent, products "not made or used in, or imported into, the United States" may infringe if there is a "domestic location of sale." Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd., 807 F.3d 1283, 1310 (Fed. Cir. 2015). They claim that, after propounding specific interrogatories as directed, they have identified thirty-two contracts, with sixteen counterparties, all executed in June 2021 or prior (when Defendant had only U.S.-based employees), for which there is a basis to pursue further discovery into whether these contracts constituted United States sales. Plaintiffs seek significant information about these contracts, as well as supplemental information regarding post-2021 contracts.

20. Defendant objects, contending that Plaintiffs' motion is an ongoing attempt to fabricate a hypothetical scenario where manufacturing and sales of a product occurring entirely outside the United States can somehow constitute a "U.S. sale."
21. Section 271(a) of the patent statute provides in relevant part that "whoever without authority makes, uses, *offers to sell*, or *sells* any patented invention, *within* the United States . . . infringes the patent." 35 U.S.C. § 271(a) (emphases added); Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 441 (2007) ("It is the general rule under United States patent law that no infringement occurs when a patented product is made and sold in another country."). Sales for products "manufactured, delivered, and used entirely abroad," may be found to have occurred in the United States—and thus infringing under § 271(a)—where a "substantial level of sales activity" occurred in the United States. Carnegie Mellon Univ. v. Marvell Tech., 807 F.3d 1283, 1309–10 (Fed. Cir. 2015). And products "not made or used in, or imported into, the United States" may infringe if there is a "domestic location of sale." Id. at 1310.
22. Determining where a sale occurred is a fact-specific inquiry, in which Halo Court noted that "[a]lthough the place of contracting may be one of several possible locations of a sale to confer personal jurisdiction, we have not deemed a sale to have occurred within the United States for purposes of liability under § 271(a) based solely on negotiation and contracting activities in the United States when the vast majority of activities underlying the sales transaction occurred wholly outside the United States." Halo, 831 F.3d at 1378. "For such a sale, one must examine whether the activities in the United States are sufficient to constitute a 'sale' under § 271(a), recognizing that a strong policy against extraterritorial liability exists in the patent law." Id. The Federal Circuit remarked that, "[w]hile we have held that a sale is 'not limited to the transfer of tangible property' but may also be determined by 'the agreement by which such a transfer takes place,' . . . the location of actual or anticipated performance under a 'contract for sale' remains pertinent to the transfer of title or property from a seller to a buyer." Id. (internal

quotations omitted). The Court emphasized that “when substantial activities of a sales transaction, including the final formation of a contract for sale encompassing all essential terms as well as the delivery and performance under that sales contract, occur entirely outside the United States, pricing and contracting negotiations in the United States alone do not constitute or transform those extraterritorial activities into a sale within the United States for purposes of § 271(a).” Id. Faced with the plaintiff’s evidence that defendant engaged in pricing negotiations in the U.S. and certain contracting and marketing activities took place in the U.S., which resulted in purchase orders and sales overseas, the Court held that such activities did not render the sales to be U.S. sales, particularly given “the presumption against extraterritorial application of United States laws.” Id.

23. The question here is somewhat different than that at issue in Halo as I need not determine whether Plaintiffs have definitively proved that certain sales were “U.S. sales” but only whether Plaintiffs have substantiated their request for additional discovery into these sales. After review of all submissions, I find that they have not.

24. As noted above, I provided Plaintiffs an opportunity to propound specific interrogatories upon Defendant to determine the nature of many of Defendant’s sales. Plaintiffs do not dispute that Defendant provided substantial information in response. Based on that discovery, Plaintiffs have only been able to show that certain contracts were negotiated by an employee based in the United States, that some sales orders were “processed” in the United States, that the contracts were signed by a “U.S.-based employee,” that marketing teams were based in the United States, that certain contingency provisions in the foreign sales contracts specifically required U.S. FDA approval of the vaccine, and that design work for the Accused Product occurred from the United States. In response, Defendant notes that (a) there was no physical location of contract negotiations as all of them were conducted remotely during the pandemic, (b) sales orders were originated by foreign customers abroad and only processed with the assistance of U.S.-based

personnel up until January 2021, (c) Moderna Switzerland GmbH was the contracting entity for each contract regardless of whether a particular contract was physically signed by a U.S.-based employee, (d) the place of delivery and other substantial sales activities occurred abroad, and (e) any marketing information sent out of the U.S. is modified by foreign marketing teams. Ultimately the products sold under those contracts were made, warehoused, sold, and delivered entirely abroad.

25. Plaintiffs have identified nothing more than U.S.-based pricing and contracting negotiations, physical execution of the contracts, and some marketing activities. Evidence of activities that led up to the contracts—signed on behalf of a foreign-based Moderna division—are insufficient to transform the sales made under these contracts into U.S. sales, particularly where the production, sales, storage, and distribution of the products all occurred outside the United States. Absent at least some evidence of significant sales activity within the United States, Plaintiffs cannot substantiate their efforts to take wide-reaching discovery into these contracts in order to somehow argue that they constitute U.S. sales under § 271(a).

26. As to the post-2021 contracts, Plaintiffs concede that the contracts identified in Defendant's interrogatory responses were consummated through foreign-based Moderna employees. Nonetheless, Plaintiffs request that Defendant be ordered to supplement its interrogatory responses so that they can independently assess whether further targeted discovery is warranted as to the specific contracts. Plaintiffs, however, must show that this request “is premised on more than ‘mere suspicion or speculation’ as to how the discovery is linked” to the infringement allegations in this case. Tessera, Inc. v. Broadcom Corp., No. 16-cv-380, 2017 WL 4876215, at *5 (D. Del. Oct. 24, 2017) (quotations omitted). I find that Plaintiffs have not met this burden.

27. Accordingly, I will deny Plaintiffs' letter motion for additional discovery regarding Defendant's foreign sales of the Accused Product.

Defendant's Motion for Lobbying Materials from Both Plaintiffs and Third-Party Roivant

28. The next discovery dispute at issue concerns the parties' mutual requests for "lobbying" materials. At the hearing, the parties advised that they had reached a partial agreement wherein Plaintiffs would produce documents and communications with lobbyists and political consultants concerning Defendant, the Spikevax vaccine, the current action, the United States Government's Statement of Interest, and/or the C-0100 contract, while Defendant would reciprocate and produce its own communications with lobbyists about this action, the Statement of Interest, appropriations for the COVID-19 vaccine, and the application of § 1498 to either of Defendant's contracts with the U.S. Government.
29. Purportedly, after this agreement was reached, Plaintiffs conditioned their production of the lobbying documents upon Defendant's additional production of non-lobbying materials involving Defendant's communications with all federal agencies and communications that relate to its assertion of the § 1498 defense. Defendant has argued that it has a common interest privilege with the U.S. Government and should not be compelled to produce these documents in order to obtain Plaintiffs' lobbying documents.
30. At the discovery hearing, I pressed the parties regarding the relevance of lobbying activities on the core allegations at issue in this case and was unconvinced that such evidence has any bearing on the issues at play. Nonetheless, as the parties themselves have agreed to a mutual exchange of "lobbying" documents, I will reluctantly order that such documents be provided by each party within ten (10) days from the date of this Order.
31. The only remaining question is whether Defendant must produce non-lobbying material including Defendant's communications with all federal agencies regarding this action, the Statement of Interest, appropriations for the COVID-19 vaccine, and application of § 1498 the Moderna-U.S. contracts at issue.

32. Defendant argues that this information is protected by the common interest or joint defense privilege. This privilege is “an exception to ordinary waiver rules designed to allow attorneys for different clients pursuing a common legal strategy to communicate with each other.” Waymo LLC v. Uber Techs., Inc., 870 F.3d 1350, 1359 (Fed. Cir. 2017) (quotations omitted). The party seeking to invoke the doctrine must first establish that the communicated information would otherwise be protected from disclosure by a claim of privilege and then must demonstrate that the communication was made in pursuit of common legal claims including common defenses. Id. at 1359–60.

33. Defendant has not met its burden of establishing this privilege in its communications with the U.S. Government. Indeed, it is hard to comprehend how Defendant and the Government share a common legal defense since, under 28 U.S.C. § 1498, either the Government or Defendant—not both—will be responsible for any infringement damages.

34. Moreover, as I found above with respect to Plaintiffs’ request for Rule 30(b)(6) testimony, evidence regarding Defendant’s communications with the Government regarding the vaccine, the Government contracts, and the Statement of Interest is essential to the defense that Defendant mounted and continues to pursue under 28 U.S.C. § 1498. Accordingly, I will order production of these documents within fourteen (14) days from the date of this Order.

Plaintiffs’ Oral Request for Raw Data Underlying Certificates of Analysis for Batches of the Vaccine Made by Third-Party Manufacturers

35. At the hearing, Plaintiffs made an oral request for the raw data underlying certificates of analysis produced by Defendant for batches of its vaccine. Defendant agreed to produce that material for the batches it manufactured but not for third-party manufacturers. Defendant also represented that it reached out to the third-party manufacturers, to no avail, regarding that production.

36. Although Plaintiffs claim that it would be “easier” for Defendant to obtain this discovery from manufacturers with whom it has a business relationship, I decline to impose the burden on Defendant beyond the efforts already undertaken.

37. I will, however, extend the discovery period to permit Plaintiffs to subpoena the requested documents from the third-party manufacturers. Specifically, Plaintiffs may, within ten (10) days from the date of this Order, issue subpoenas to the following twelve entities for production of the raw data underlying the lipid content measurements in the certificates of analysis that they have generated for Defendant:

- Lonza Biologics, Inc.
- Lonza AG
- Rovi Pharma Industrial Services, S.A.Q.
- Catalent Indiana, LLC
- Catalent Anagni S.r.l.
- Recipharm Monts
- Patheon Manufacturing Services, LLC
- Thermofisher Ferentino
- Patheon Italia S.p.a.
- Baxter Pharmaceutical Solutions, LLC
- Eurofins Biopharma
- Samsung Biologics Co. Ltd.

WHEREFORE, it is hereby **ORDERED** that the discovery motions are **GRANTED IN PART** and **DENIED IN PART** as set forth herein. The fact discovery deadline is extended to **July 17, 2024**, for the sole purpose of completing the ordered discovery. No other deadlines in the current schedule shall be amended at this time.

BY THE COURT:

/s/ Mitchell S. Goldberg

MITCHELL S. GOLDBERG, J.